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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,429	12/21/1999	RICHARD C. BOUCHER JR.	5470-250	8856

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[REDACTED] EXAMINER

WANG, SHENGJUN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1617

DATE MAILED: 07/16/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/465,429	BOUCHER, RICHARD C.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 February 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 22-50 is/are pending in the application.
- 4a) Of the above claim(s) 25-29,33-36,38-43,45-48 and 50 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 22-24,31,32,37,44 and 49 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                           | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

1. Claims 25-29, 33-36, 38-43, 45-48, 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Papers No. 8 and 12.
2. Applicant's election without traverse of invention II, claims 22-29 and newly added claims 31-50 in Paper No. 6, and the species sodium channel blocker as the active ingredient, in Paper No. 8, and potassium sulfate as the osmolyte, cystic fibrosis as the disease afflicting the subject, and inhalation as the administer method in paper No. 12, is acknowledged.
3. The claims have been examined insofar as they read on elected species.

### ***Claim Rejections 35 U.S.C. 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 22-24, 31-32, 37, 44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (IDS, 5) in view of Boucher, Jr. et al. (U.S. Patent 5,876,700) and Jungherr et al. (U.S. Patent 5,837,266).
6. Andersons teaches a method of increasing mucociliary clearance or inducing sputum comprising the step of causing a subject to inhale into subject's airway an osmolyte to increase the osmolarity of airway surface liquid. See, particularly, claims 12-21. the osmolyte may be any substance that is biologically compatible with the subject, preferably mineral salts, and more

preferably sodium and potassium salt. See, column 3, lines 12-25, and claims 15 and 16. The method is known to be useful for subject having cystic fibrosis. See, column 2, lines 14-33.

7. Anderson does not teach expressly administering a sodium channel blocker agent with an osmolyte for treating cystic fibrosis, or employ potassium sulfate as the osmolyte.

8. However, Boucher, Jr. et al. teach a method for hydrating mucous secretions in lungs, or for treating cystic fibrosis comprising administering to the patient by inhalation benzaminil or phenamil, the sodium channel blocker employed herein. See, particularly, the abstract, claims 1-5, 7-10, and 12-16. Jungherr et al. teaches that potassium sulfate is known to be biological compatible with human and is known to be useful in therapeutical composition as osmolyte. See, particularly, column 3, lines 26-33.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to treat a subject with cystic fibrosis by administering to the subject a combination of osmolyte, such as potassium sulfate and a sodium channel blocker, such as benzaminil or phenamil.

A person of ordinary skill in the art would have been motivated to treat a subject with cystic fibrosis by administering to the subject a combination of osmolyte, such as potassium sulfate and a sodium channel blocker, such as benzaminil or phenamil because it is prima facie obvious to combine two agents each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus , the claimed invention which is drawn to a method for treating cystic fibrosis employing a combination of two agents, each of them is known to be useful for treating cystic fibrosis, sets

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forth *prima facie* obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. The employment of potassium sulfate is seen to be a selection from amongst equally suitable potassium salts, particularly because potassium sulfate is known to be biological compatible to human and is known to be used as osmolyte in therapeutical composition. Ex parte Winters 11 USPQ 2<sup>nd</sup> 1387 (at 1388).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

July 8, 2002